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## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

09404.0005-02000

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on \_\_\_\_\_

Signature \_\_\_\_\_

Typed or printed name \_\_\_\_\_

Application Number

10/666,440

Filed

September 19, 2003

First Named Inventor

Timothy John HENKEL

Art Unit

1618

Examiner

M.P. Young

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐

applicant/inventor.



Signature

☐

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.

Steven P. O'Connor

Typed or printed name

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attorney or agent of record.

Registration number 41,225

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attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

June 1, 2006

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

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\*Total of 1 forms are submitted.

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PATENT  
Customer No. 22,852  
Attorney Docket No. 09404.0005-02

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)	
Timothy John HENKEL	)	Group Art Unit: 1618
Application No.: 10/666,440	)	Examiner: M.P. YOUNG
Filed: September 19, 2003	)	
For: METHODS OF TREATMENT	)	Confirmation No.: 8311

**Mail Stop AF**  
**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, VA 22313-1450**

Sir:

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

In reply to the final Office Action mailed March 17, 2006, Applicant respectfully requests panel review of the twice-rejected claims. No amendments are being filed with this Request. This Request is due June 17, 2006, and is timely filed. A Notice of Appeal accompanies this Request.

**REMARKS**

**I. Status of the Claims**

Claims 1-42 are pending and under consideration.

**II. Rejections Under 35 U.S.C. §§ 102(b) and 103(a)**

Claims 1, 4-8, 11-26, 34 and 35 stand rejected as anticipated by, and claims 2, 3, 9, 10, 27-33 and 36-42 stand rejected as obvious over, File *et al.*, J. Chemotherapy, Vol. 12, pages 314-25 (August 2000) ("File"). Office Action, page 2 and 3. Applicant again respectfully traverses these rejections because File is not available as a reference under any section of 35 U.S.C. § 102.

In a Request for Reconsideration filed December 8, 2005, Applicant provided evidence in the form of a date stamp that the library at the National Institutes of Health did not receive the Journal of Chemotherapy, volume 12, no. 4 until November 3, 2000, a date on or after Applicant's effective filing date. It is the Office's position that the NIH date stamp is insufficient because "[u]nless conclusive evidence can be provided that the publisher of the article actively withheld the volume 12 issue of the Journal of Chemotherapy, there is no evidence to support that the article was not available until November of 2000." Office Action, page 5.

It is the Office, not the Applicant, that bears the burden of determining the issue or publication date of a reference so that a proper comparison between the application and reference dates can be made. M.P.E.P. 706.02(a)(I). As previously noted, a journal article is not available as prior art *until* it is received by a member of the public. M.P.E.P. § 2128.02 (citing *In re Schlittler*, 234 F.2d 882, 110 U.S.P.Q. 304 (CCPA

1956). Applicant has provided evidence in the form of a date stamp that File was not received by a member of the public until November 3, 2000. The date stamp is the only evidence in the record regarding the date on which File was received by a member of the public.

Although it provides no evidence in support of its position, the Office also speculates that the reference may have been available on-line or with another library before November 2000. Office Action, pages 4-5. While Internet disclosures and on-line databases can be relied upon by the Office, their date for the purposes of determining their availability as prior art is the date the item was publicly posted. M.P.E.P. 2128. If the publication does not include a publication date (or retrieval date), it cannot be relied upon as prior art under 35 U.S.C. 102(a) or (b). *Id.* The Office's unsupported speculation is not a determination of the issue or publication date. Thus, there is no evidence that the File reference was publicly posted on the Internet before Applicant's effective filing date.

Applicant has provided evidence that File was not publicly available until November 3, 2000. This application claims benefit of provisional application no. 60/232,809, filed September 15, 2000, and provisional application no. 60/245,744, filed November 3, 2000. Consequently, File is not available as a reference under 35 U.S.C. § 102(b), nor is it a reference under 35 U.S.C. § 102(a) because that section requires that the reference describe the invention in a printed publication "*before* the invention thereof by the applicant for patent in the United States." 35 U.S.C. § 102(a) (emphasis added). Applicant therefore respectfully requests withdrawal of the rejections of record under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) based upon the File reference.

**Conclusion**

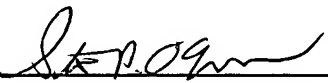
In view of the foregoing remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: June 1, 2006

By:   
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